

§ 26.1117

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10543, Feb. 14, 2013]

§ 26.1117 Documentation of informed consent.

(a) Informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject. A copy shall be given to the subject.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 26.1116. This form may be read to the subject, but in any event, the investigator must give the subject adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 26.1116 have been presented orally to the subject. When this method is used, there must be a witness to the oral presen-

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tation. Also, the IRB shall approve a written summary of what is to be said to the subject. Only the short form itself is to be signed by the subject. However, the witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the subject, in addition to a copy of the short form.

[78 FR 10543, Feb. 14, 2013]

§§ 26.1118–26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.